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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,217	07/30/2003	Nathaniel T. Becker	GC515-2-US-C1	8779

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,217	BECKER ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A preliminary amendment of 11/7/03 canceled claims 1-11, and added new claims 12-31.

Claims examined on the merits are 12-31, which are all claims in the application.

Claim Objections

Claims 29-31 are objected to because of the following informalities: the claims are not indicated as being new claims by reciting "(new)" after the claim number. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for methods using temperatures and comparing with a test granule as required by claims

29-31. The page and lines should be pointed out where methods as required by the claims are described.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the last line of claim 12, line 4 of claim 25, and line 5 of claim 29, "moderate or high water activity" is uncertain as to meaning and scope. Being "moderate" and "high" is relative and subjective.

In line 4 of claim 29, and bridging lines 3 and 4 of claim 30, "slightly below" is uncertain as to meaning and scope. Being "slightly below" is relative and subjective.

In claims 29 and 31, the method of preparing the test granule has not been set forth in sufficient detail to know whether the greater retained enzyme or protein activity is significant. In line 7 of claim 29, "similar test granule" is uncertain as to meaning and scope since being "similar" is relative and subjective.

Requiring an outlet temperature in claims 29 and 30, line 4, is confusing since no structure having an outlet is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-16 and 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Herdeman (4,707,287).

The claims are drawn to a granule having a protein core and a hydrated barrier material coating over the protein core, and the granule having a moderate or high water activity.

Herdeman discloses a granule having a enzyme core (col 5, line 5) that can be ALCALASE (col 6, line 10), a protective coating of alkaline buffer salt around the core (col 2, lines 15-35, and col 3, lines 43-47), a water-soluble nonionic waxy overcoating that can be polyethylene glycol, and a coating of acetate phthalate resin (col 2, lines 50-60, and col 7, lines 15-17). The granule has a moisture content of 3-10% (col 7, lines 10-11).

The granule of Herdeman is the same as presently claimed. When the granule of Herdeman has 3-10% water, the barrier will be hydrated, and the granule will have a water activity of moderate or high, or within ranges of dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herdeman in view of Painter et al (5,292,446) and Dychdala et al (3,793,216).

The claims require a hydrated inorganic salt as the barrier selected from salts that are a heptahydrate, dehydrate or tetrahydrate.

Painter et al disclose using sodium citrate dehydrate (col 9, lines 15-16) as an alkaline salt in a washing composition.

Dychdala et al disclose using different hydrated inorganic salts including sodium phosphate dibasic heptahydrate (col 3, lines 63-64) to provide a water content of 3-13% (col 9l line 29).

It would have been obvious to use as the alkaline buffer salt of Herdeman a hydrated alkaline salt as taught by Painter et al and Dychdala et al to maintain the moisture content 3-10% desired by Herdeman as suggested by Dychdala et al using a hydrated salt to maintain a moisture content of 3-13%.

Claim Rejections - 35 USC § 103

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 17 and 27 above, and further in view of Arnold et al (5,324,649).

The claim requires an enzyme core to comprise a seed particle coated with an enzyme.

Arnold et al disclose producing a granule containing an enzyme coated on a core particle (col 2, lines 13-39).

It would have been obvious to provide the enzyme core of Herdeman by coating the enzyme on a particle as suggested by Arnold et al, when using a hydrated salt as the barrier coating on the enzyme core as set forth above.

Claim Rejections - 35 USC § 103

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herdeman.

The claims are drawn to methods of preparing the granule.

The method for granule preparation disclosed by Herdeman is the same as presently claimed except for temperatures required by the claims. Selecting preferred optimum temperatures for preparing the granule of Herdeman would have required only limited routine experimentation and been obvious. A granule produced as disclosed by Herdeman will inherently have a higher enzyme activity than a test granule as required by claims 29 and 31.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,602,841 B1. Although the conflicting claims

are not identical, they are not patentably distinct from each other because the presently claimed granule having a protein core and hydrated barrier and method for preparation thereof encompasses the granule having a protein core and hydrated barrier and method for preparation thereof of the patent claims, and would have been obvious from the patent claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
2/21/06